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# Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

**Submitted by:**

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**Name/Classification of Device:**

Class II in 21 CFR § 878.4493, Absorbable poly(glycolide/l-lactide) surgical suture (GAM)

**Trade Name:**

PDS* Plus (Polydioxanone) Antibacterial Suture

**Predicate Devices:**

PDS II* (Polydioxanone) Suture (N18331)
VICRYL* Plus Antibacterial Suture (K032420)
MONOCRYL* Plus Antibacterial Suture (K050845)

**Statement of Intended Use:**

PDS* Plus Antibacterial monofilament synthetic absorbable sutures are indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and sclera). PDS Plus is not indicated in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

**Device Description:**

PDS* Plus (Polydioxanone) Antibacterial monofilament synthetic absorbable suture is prepared from a polyester, poly (p-dioxanone). The suture is available dyed (D&C Violet No. 2) or undyed (natural). The suture contains Irgacare MP** (triclosan), a broad-spectrum antibacterial agent, at no more than 2360 μg/m.

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**Summary of Technological Characteristics of New Device to Predicate Devices:**

The modified device has similar technological characteristics as the predicate devices. Like currently marketed PDS* II Suture, it is a sterile, monofilament synthetic absorbable suture that conforms to the USP Monograph for absorbable surgical sutures, except for diameter. Like the currently marketed Coated VICRYL Plus Antibacterial suture and MONOCRYL Plus Antibacterial suture, the modified device contains Irgacare** MP, an antibacterial agent.

**Performance Data:**

Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP Monograph for absorbable surgical sutures. Additionally, in-vivo/in-vitro testing was provided showing that the device performed as intended and as claimed.

**Conclusions:**

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

* *Trademark of Ethicon, Inc.*
***Trademark of Ciba Specialty Chemicals Corporation*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon, Inc., a Johnson & Johnson Co.
% Mr. Bryan A. Lisa
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Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

JUL 14 2006

Re: K061037
Trade/Device Name: PDS* Plus (Polydioxanone) Antibacterial Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: July 5, 2006
Received: July 6, 2006

Dear Mr. Lisa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K061037

Device Name: PDS* Plus (Polydioxanone) Antibacterial Suture

Indications for Use:

PDS* Plus Antibacterial monofilament synthetic absorbable sutures are indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and sclera). PDS Plus is not indicated in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brochu

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K061037